IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	10/531,184	Confirmation No. 6320
Applicant	:	Arieh Sher	
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Examiner	:	Joel Lamprecht	
Docket No.	:	798/18	

Commissioner for Patents
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RESPONSE AFTER FINAL

Sir:

In response to the Office Action of 20 June 2008, this response being filed on or before 20 August 2008 and for which no extension fees are due. Please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 9 of this paper.

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) A method for reducing restriction of blood flow in a lumen of a blood vessel caused by an intraluminal plaque therein, the method comprising:

(a) inserting an ~~non-crossing the lesion~~ imaging guidewire into the lumen of the blood vessel up to the intraluminal plaque without traversing the plaque, said imaging guidewire capable of generating a cross-sectional image of the lumen;

(b) propelling a catheter including a working head over said imaging guidewire towards said intraluminal plaque until said catheter reaches a distal end of said guidewire;

(c) scanning the lumen with said imaging guidewire to generate said cross-sectional image of the lumen;

(d) positioning said catheter in the lumen by actuating at least one positioning element;

(e) monitoring said cross sectional image to ascertain that said working head is positioned at a desired location with respect to said proximal end of the intraluminal plaque; and

(f) operating said working head to remove at least a portion of the intraluminal plaque.

2. (Original) The method of claim 1, further comprising repetition of (c) through (f).

3. (Previously Presented) The method of claim 2, iteratively repeated until the restriction in the lumen has been reduced to a desired degree.

4. (Original) The method of claim 3, further comprising advancing the catheter in the lumen.

5. (Original) The method of claim 4, iteratively repeated until said working head traverses said intraluminal plaque.

6. (Original) The method of claim 1, wherein said intraluminal plaque is of a type selected from the group consisting of a primary atherosclerotic lesion, a lesion caused by restenosis, a lesion residing at least partially within a previously implanted stent, a lesion situated in close proximity to a bifurcation of the lumen of the blood vessel, a vulnerable plaque and a lesion which totally occludes the lumen of the blood vessel.

7. (Original) The method of claim 1, wherein said working head includes at least one cutting edge which is operative only when said working head moves rotationally.

8. (Original) The method of claim 1, wherein said positioning of said catheter in the lumen is implemented such that said at least one positioning element includes at least one balloon which circumferentially surrounds at least a portion of said catheter.

9. (Original) The method of claim 1, wherein said positioning of said catheter in the lumen is implemented such that said at least one positioning element includes at least one set of at least three balloons in a single cross sectional plane of said catheter.

10. (Original) The method of claim 9, wherein said positioning of said catheter in the lumen is implemented so as to further include at least one additional set of at least three balloons in a single cross sectional plane of said catheter.

11. (Original) The method of claim 1, wherein said inserting, propelling, scanning, positioning, monitoring, operating are subject to control by a single central processing unit (CPU).

12. (Original) The method of claim 11, wherein said single CPU is further subject to input by a physician operator thereof.

13. (Original) The method of claim 1, wherein said operating said working head begins prior to a traverse of the plaque by said working head.

14. (Original) The method of claim 1, wherein said operating of said working head includes rotating said working head at a speed of 1 to 100 RPM.

15. (Original) The method of claim 1, wherein said operating of said working head includes rotating said working head at a speed of 5 to 50 RPM.

16. (Currently Amended) A system for reducing restriction of flow in a lumen of a blood vessel caused by an intraluminal plaque therein, the system comprising:

a) an ~~non-crossing the lesion~~ imaging guidewire insertable in the lumen of the blood vessel up to the intraluminal plaque without traversing the plaque, said imaging guidewire capable of generating digital data which describe a cross-sectional image of the lumen and communicating said digital data to a central processing unit (CPU) and further capable of guiding a catheter to the intraluminal plaque without traversing the plaque;

(b) a catheter including a working head, said working head designed and constructed to remove at least a portion of the intraluminal plaque;

(c) at least one positioning element integrally formed with, or attached to, said catheter, said at least one positioning element designed and constructed to position said working head within the lumen of the blood vessel;

(d) a CPU designed and configured to:

(i) accept input from a physician;

(ii) to receive said digital data which describe said cross-sectional image of the lumen and transform said digital data into said cross-sectional image displayable upon a display device;

(iii) operate actuators which control components of the system; and

(iv) control operation of said positioning element by means of at least one of said actuators; and

(e) one or more actuators, subject to control by said CPU and including:

(i) at least one positioning element actuator responsible for the control of said at least one positioning device.

17. (Currently Amended) The system of claim 16, wherein said CPU is further designed and configured to perform at least one action selected from the group consisting of:

([[~~iv~~]] i) to rotate said guidewire within said catheter by means of said actuators; and

([[~~v~~]] ii) control operation of said working head.

18. (Original) The system of claim 16, wherein said CPU further includes at least one item selected from the group consisting of a display device and a data input device.

19. (Currently Amended) The system of claim 16, wherein said actuators further includes at least one additional actuator designed and constructed to perform at least one action selected from the group consisting of:

([[~~ii~~]] i) longitudinally reciprocate and rotate said working head;

([[~~iii~~]] ii) advance said catheter within the lumen;

([[~~iv~~]] iii) rotate said guidewire within said catheter; wherein said actuators are subject to control of said CPU.

20. (Currently Amended) The system of claim 16, wherein said working head is configured to operate[[s]] intermittently as said catheter traverses said intraluminal plaque.

21. (Original) The system of claim 16, wherein said working head includes at least one cutting edge which is operative only when said working head moves rotationally.

22. (Original) The system of claim 16, wherein said at least one positioning element includes at least one balloon which circumferentially surrounds at least a portion of said catheter.

23. (Original) The system of claim 16, wherein said at least one positioning element includes at least one set of at least three balloons in a single cross sectional plane of said catheter.

24. (Original) The system of claim 23, further including at least one additional set of at least three balloons in a single cross sectional plane of said catheter.

25. (Previously Presented) The system of claim 16, wherein said working head is configured such that operation of said working head begins prior to a traverse of the plaque by said working head.

26. (Original) The system of claim 16, wherein operation of said working head includes rotating said working head at a speed of 1 to 100 RPM.

27. (Original) The system of claim 16, wherein operation of said working head includes rotating said working head at a speed of 5 to 50 RPM.

28. (Original) The system of claim 16, wherein said imaging guidewire further includes a folding mirror and wherein said catheter is positionable upon said guidewire so that only said folding mirror protrudes from said working head in a direction facing the plaque.

29. (Original) The system of claim 16, wherein an Archimedes screw is further incorporated into the design of said imaging guidewire in order to facilitate removal of at least a portion of the plaque.

30. (Original) The system of claim 16, wherein said catheter includes at least one therapeutic lumen.

31. (Original) The system of claim 16, wherein said catheter includes a central vacuum lumen.

REMARKS/ARGUMENTS

In the Claims

Claims 1-31 remain in this application. Claims 1, 16, 17, 19 and 20 have been amended.

Claim Objections

Claims 16-31 are objected to because of the following informalities: In Claim 16, the newly amended limitations to step a) do not set forth any additional structural limitations. Examiner has stated that it is unclear from the specification what structural differences are explicitly defined by "non-crossing the lesion imaging guidewire".

Applicant acknowledges the Examiner's comments and points out that the same limitation is recited in claim 1 as well. In order to bring the instant application into better condition for Appeal, Applicant has amended both claim 1 and 16 by deleting the unclear phrase "non-crossing the lesion".

Regarding claim 20, line 2, "operates" has been amended to read "operate", as requested by the Examiner.

Further, Applicant has amended claims 17 and 19 to correct erroneous numbering of the subsections of each claim.

Applicant respectfully points out that the above amendments serve to make the claims more clear or correct typographical errors and do not affect the scope of the claims as pointed out by the Examiner in his objection to claim 16 on page 2 of the current Office Action. Therefore, application requests that the Examiner enter these amendments into the record.

§ 103 Rejections

The Examiner has rejected claims 1-13, 16-25, 28 and 30-31 under 35 U.S.C. 103(a) as being unpatentable over McKenzie et al. (5,993,469) in view of Pomeranz (US 5,938,609) and in further view of Selmon et al. (US 2001/0018596 A1); claim 29 is rejected in further view of Findlay (6,623,495); and claims 14, 15, 26 and 27 in further view of Masch (4,728,319). The Examiner's rejections are respectfully traversed.

Applicant respectfully asserts that a device constructed and operative according to the combined teachings of McKenzie et al., Pomeranz and Selmon et al. is a) patently distinguished from the present invention and b) would be inoperable.

Turning first to McKenzie et al., McKenzie et al. does not teach the usage of an imaging guidewire. He mentions as prior art guidewires and imaging modalities, but does not incorporate them into his device. This is expressed explicitly in column 6, line 67;

> "...Advancement may be assisted by IVUS or TEE or by a conventional guide wire..." (emphasis added)

However, McKenzie et al. does not discuss in the specification or show in his drawings how a guidewire is incorporated in his device.

Regarding Pomeranz, Applicant is fully aware of Pomeranz as mentioned in the instant application on page 5, line 15.

There are substantial differences between the imaging guidewire described in the instant application and the imaging guidewire/catheter described by Pomeranz.

Firstly, from a structural point of view, the imaging catheter of Pomeranz contains a fixed guide wire (elements 18, 58, and 78 in Fig. 1, Fig. 2 and Fig. 3 respectively). This fixed guidewire extends freely distally to the catheter. The imaging elements (e.g., transducer 34) of the catheter are located proximally to the fixed guidewire.

This is in contrast to the imaging element disclosed on the instant application. Folding mirror (17) is located at the tip of the guidewire (16) adjacent to the cutter (6). Moreover, in Fig. 6 it is shown that an effort was made so that only the folding mirror (17) extends distally from the cutter (6). Other imaging parts (lens 18) reside inside the cutter (6). This construction is done in order to minimize the part of the imaging guidewire that freely extends in front of cutter (6). The imaging guidewire is supported by the catheter and therefore the axial compression force that can be applied to the distal tip of the imaging guidewire is substantially higher then this of Pomeranz fixed guidewire.

Secondly, from an operational point of view, Pomeranz teaches in column 7, line 30-37;

> "...after the guidewire tip 18 enters the branch, the catheter 10 is moved forward so that the housing 16 is able to enter the stenosed region S. The guidewire tip 18 will than extend beyond the stenosed region.... The imaging system 30 within the housing 16 may then be used to image the stenosed region..." (emphasis added).

It is to be noted that Pomeranz relates also to a regular guidewire, which is designated as a "movable guidewire" in column 1, line 61-67;

> "...The moveable guidewire is first positioned within the vascular system so that its distal end extends beyond the region of interest..." (emphasis added)

Clearly, Pomeranz teaches that the guidewire, either fixed guidewire or movable guidewire, is forced to cross the lesion by itself and that any imaging system incorporated into the guide wire is located proximally to the tip of the guidewire.

Contrary to that, the instant application clearly teaches that the imaging guidewire is not forced to cross the lesion by itself. Therefore it is designated as "non-crossing the lesion imaging guidewire". It is first used as a regular guidewire that is threaded up to the lesion. Then the catheter is advanced over the guidewire up to its

distal end. From that point on, the guidewire is used for imaging. The lesion is crossed by the catheter and the guidewire as one unit.

This mode of operation makes the device of the application suitable for crossing partial occlusions as well as CTO. CTO is a serious problem in angioplasty and occurs in about 30% of all angioplasty procedures. CTO is an occlusion that cannot be crossed by a standard guidewire. Crossing the lesion is a mandatory requirement for many angioplasty procedures. Therefore, in cases when the guidewire cannot cross the lesion, the patient cannot be treated by angioplasty and is referred to other medical procedures, usually by-pass surgery.

Turning now to Selmon et al., unlike the devices of Pomeranz and McKenzie et al., the device that is described by Selmon et al. is not an atherectomy device. Atherectomy devices cut out the atheroma. ("Cut out the atheroma" is the meaning of "atherectomy" in Greek). Selmon et al.'s device does not cut out the atheroma, but merely creates a pathway in the atheroma by using expansion members (202). Quoting the Abstract;

> "...The tissue expansion members may stretch apart, tear or otherwise disrupt a vascular occlusion sufficiently to create a pathway that may support the passage or placement of a guidewire or an interventional vascular device across the occlusion or obstruction". (emphasis added)

The Selmon et al. device belongs to a group of special guidewires, known in the art as, stiff guidewires (by Boston Scientific, J&J etc.), worm type guidewire (US20070083220), and Vibration guidewire (Crosser by Flowcardia).

The guidewire in Selmon et al. is not an imaging guidewire but rather a standard guidewire. The term "imaging" is not mentioned by Selmon et al. in connection with guidewire (28). Applicant would like to point out that Applicant was aware of the Selmon et al. device. The instant application cited an earlier patent to Selmon (US

6,120,516) as an example of a device for crossing total occlusions. In '516 Selmon is aware of the importance of imaging in angioplasty procedures and teaches incorporation of an imaging capability in the device. However the imaging is done by optical fiber or fibers that are not a part of the guidewire. Fig. 1 shows one optical fiber (208) that is installed in the catheter body, Fig 6 shows multiple fibers (236) installed in the catheter body. It is clear that Selmon does not teach usage of an "imaging guidewire". Fig. 18 and Fig. 19 of '516 describe an embodiment that is later described in detail in US 6,800,085. The guidewire of this embodiment is a regular guidewire (114).

Further, the operation of Selmon et al. device clearly teaches that the device is used to facilitate deployment of a guidewire across the occlusion as described throughout the specification. Most specifically in paragraphs [0002], [0008], [0014]-[0017], [0052], [0056], [00592], [0074], [0077], [0094] and [0096], as exemplified in paragraph [0015], which states;

> "The guidewire may extend along to the length of the catheter and reach the site of an occlusion. Upon activation of at least one spreading member, the guidewire may be advanced through or around at least a portion of the occlusion." (emphasis added)

The Examiner learns from Selmon et al. the use of a guidewire up to the occlusion only. Further, the Examiner learns the use of an imaging guidewire from Pomeranz. Since Pomeranz is the only reference of the three that teaches use of an imaging guidewire, the combination suggested by the Examiner must then include the guidewire taught by Pomeranz, which includes a length of guidewire extending distally from the imaging system.

Clearly it is not possible to incorporate an imaging guidewire as described by Pomeranz into the Selmon et al. device because neither the fixed guidewire nor the imaging system can cross the total occlusion before the jaws create a passage in the

occlusion. Pomeranz does not exactly define the length of the fixed guidewire extending in front the imaging system. Therefore, one of ordinary skill in the art may suggest eliminating the fixed guidewire so that the imaging system is located at the tip of the guidewire. Such an embodiment will encounter a number of problems.

Pomeranz needs the extending tip to steer his guidewire. Selmon et al. on the other hand does not disclose, hint or suggest a way to steer his guidewire if an imaging system were deployed at the tip. Therefore, in would be impossible to position a Selmon et al. guidewire configured with a Pomeranz imaging system at the tip.

Another problem is structural, if the Selmon et al. jaws are moved to the end of such a guidewire and encounter the Pomeranz imaging system, the two will compete for the same space at the tip of the guidewire. In order to accommodate the Pomeranz imaging system structure of the Selmon et al. jaw must be modified and the strength of the jaws will be diminished because the thickness of the jaws will, by necessity, be reduced.

A third problem is more severe, this combination will not allow generating of a cross sectional view of the artery. In order to allow generation of a usable cross sectional view of the artery the imaging system must be located in a place, such that the ultrasonic wave can reach the artery wall undisturbed. However, any imaging system encased in the metal jaws of Selmon et al. would not be able to function properly. The metal jaws are an acoustic barrier to the ultrasonic waves, preventing them from reaching the artery walls.

Therefore, Applicant asserts that there is neither hint nor suggestion in either Pomeranz or Selmon et al. to combine the teachings of each and deploy the imaging system at the tip of the guidewire.

Therefore, Applicant asserts that the device of the instant application is patentably distinct from such a combination in that substantially no length of the guidewire extends beyond the elements of the imaging system. to the contrary, the imaging system is located at the tip of the guidewire.

Further, operationally, a combination of McKenzie et al., Pomeranz and Selmon et al. would be inoperable. McKenzie et al. describes at least 14 different operational tips, all of which would be rendered inoperable by the presence of the transducer of the imaging guidewire of Pomeranz since the transducer and the extending guidewire tip would make it impossible for the operation tip to reach the occlusion. Even if one skilled in the art were to redeploy the transducer to the tip of the guidewire, Applicant asserts that the McKenzie et al. operational tips could not be modified to accommodate such an imaging guidewire and still function.

Therefore, Applicant maintains that a device constructed according to a combination of the teaching of McKenzie et al., Pomeranz and Selmon et al. as suggested by the Examiner would be inoperable.

Therefore, Applicant respectfully asserts that rejection of claims 1 and 16 on the ground of the combination of McKenzie et al. in view of Pomeranz in further view of Selmon et al. is clearly inappropriate. Applicant respectfully request that the rejections be withdrawn.

Regarding Masch, Masch describes a catheter that rotates at 10-60 RPM. However, this rotation speed relates to the rotation of shaft 42 that is a part of drive assembly 18 (Column 6, Line 46). The rotation is eventually transferred via worm gear 41 to tube 16 that is connected at its distal part to cutting head 20. Masch does not actually define the rotation of the cutting head 20. In ARIO the RPM relates to the working head itself. In fact, ARIO's driving unit cannot be compared to the Masch

drive assembly. While in Masch the drive assembly is a motor that rotates a flexible tube 16, the ARIO driving unit is a linear actuator (55 in Fig. 13) that repeatedly reciprocates a pushable shaft (1 in Fig. 1). This fact is a basic distinction between ARIO and Masch, as well as all other atherectomy devices that use a flexible torque tube to rotate a cutting head.

There is no problem in building and controlling a motor outside the patient body that can provide any specified power, torque or RPM. The technological challenge of atherectomy devices, that use a torque tube, is to transfer the power from a driving unit located outside the patient body to the cutting head that is located ~1.35 meter distally from the motor via a flexible torque tube that is ~1.8 mm in diameter. The torsion stiffness of this flexible torque tube is low and the cutting head will rotate at a lower speeds than the motor. It may also happen that when encountering hard plaque the cutting head may not rotate at all.

ARIO uses a pushable shaft rather than a flexible torque tube, thus bypassing the problem of torsion stiffness. The torque that is transferred to the cutting head via ARIO's mechanism is significantly higher than that of the flexible torque tube. Therefore, ARIO's cutting head can rotate at a low RPM and yet have effective cutting power.

Regarding Findlay et al., the present invention does not claim that the usage of Archimedes screw in atherectomy devices for evacuating debris is new. Findlay describes a device that has a "rotatable member 34 comprises a generally cylindrical or tubular body 56 from which a continuous helical screw thread 58 radially outwardly extends". This construction is built specifically for debris evacuation. The guidewire (28) that is used in Findlay device is a regular guidewire.

On the other hand in ARIO the Archimedes screw (67) is a part of the imaging guide wire (Fig. 15). The present invention merely exploits the fact that in some imaging modalities the guidewire must be rotated in order to generate a cross sectional view of the artery. While rotating, the imaging guidewire can also facilitate the debris removal.

The Applicant believes that the above comments completely overcome the Examiner's rejections of claims 1 and 16 on §103(a) grounds, and therefore the rejections of claims 2-15 and 17-31, which depend therefrom, are now rendered moot.

In view of the above remarks, it is respectfully submitted that the claims are in condition for allowance.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,
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